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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,317	01/27/2004	M. Peter Marinkovich	33828/US/RFT/RMK	1212

32940 7590 03/02/2006

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EXAMINER	
TIDWELL, JUDY LILLE	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,317	MARINKOVICH, M. PETER	
	Examiner	Art Unit	
	Judy Lille Tidwell, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/17/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a composition for treating squamous cell carcinoma (SCC) comprising and antibody that specifically binds a migration facilitating protein (MFP) comprising a laminin 5 α 3 G4 and/or G5 domain or subdomain thereof and a pharmaceutically acceptable carrier, classified in class 530, subclass 387.1.

II. Claims 14-23 drawn to a method of treating SCC in a patient comprising administering a therapeutically effective amount of one or more antibodies in a pharmaceutically acceptable carrier, wherein one or more said antibodies is capable of specifically binding a laminin 5 G4 and/or G5 domain or subdomain thereof, classified in class 424, subclass 130.1.

III. Claims 24-35, drawn to a method for diagnosing the presence of SCC comprising contacting a sample with an antibody to MFP of a laminin 5 G4-5 domain or subdomain thereof, classified in class 424, subclass 130.1.

IV. Claims 36-37, drawn to a method of identifying a candidate binding agent capable of specifically binding a MFP of a laminin 5 α 3 G4 and/or G5 domain or subdomain thereof, classified in class 435, subclass 7.1.

V. Claims 38-40, drawn to a method of screening for candidate agents that inhibit SCC tumorigenesis, classified in class 435, subclass 7.1.

VI. Claims 41-43, drawn to a method of evaluating the effect of a candidate SCC drug in a patient, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I and the inventions of Groups II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the invention of Group I can be used in a materially different process. Furthermore, the inventions of Groups I versus II-VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-VI.

The inventions of Groups II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method of treating SCC (Group II), a method for diagnosing the presence of SCC (Group III), the method of identifying a candidate binding agent capable of specifically binding a MFP (Group IV), the method of screening for candidate agents that inhibit SCC tumorigenesis (Group V) and the method of evaluating the effect of a candidate SCC drug in a patient (Groups VI) are unrelated as the comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for the use of an agent, treatment, inhibition, delivering, and inducing an immune response differ significantly for each of the materials. For the use of an agent, any agent such as a small organic compound, peptide, antibody or inorganic compound may be used. For treatment, the vector is administered to a patient having cancer using any mode of administration. For delivering a cytotoxic agent to a cell, any cytotoxic agent may be conjugated to an antibody. For inducing an immune response, a B-cell, cytotoxic T-cell, or helper T-cell may be used. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups VIII-IX and XI-XV are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II-VI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II-VI.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Groups I-III contains a genus of patentability distinct species. The species are the following amino acid sequences of an antibody that specifically binds to MFP: SEQ ID NO: 13, 15, 17, 19, 21, 23. The SEQ ID NOs are all different antibodies recognizing different epitopes of MFP. As such, each species would require different searches and the consideration of different patentability issues. Accordingly, applicant must select one of each of the species within each genus.

In order to determine whether the Markush practice set forth in MPEP 803.02 must be followed, the office must assess whether members of each Markush group have unity of invention as defined by *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). The appropriate test under Harnisch for unity of invention is whether members

1) share a common utility

2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, each of the genuses and species within each genus are structurally and functionally distinct assessed on the basis of their structure and their function, even though they may have the same utility. For example, each SEQ ID NO: are different antibodies recognizing different epitopes of MFP.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT
Art Unit 1642

2-27-06
MISOOK YU
PRIMARY EXAMINER